

## REMARKS

### Formal Matters

Claims 1, 6-11 and 16-27 were examined and rejected. Claims 1, 6-11 and 16-34 are pending.

Claims 28-34 are new. These new claims are identical to claims 1-3, 11-13 and 34 in the application as originally filed. As such, no new matter is introduced by these new claims.

Applicants respectfully request reconsideration of the application and allowance of the pending claims in view of the remarks made herein.

### Rejection under 35 U.S.C. §102(a)/103(a)

Claims 1, 6-11 and 16-27 are rejected under 35 U.S.C. §102(a) as anticipated by Smith (U.S. Patent No. 5,972,294). Claims 1, 6-11 and 16-27 are also rejected under 35 U.S.C. §103(a) as obvious in view of Smith. The Office Action contends that Smith discloses a reagent test strip comprising a polysulfone membrane and 10-(carboxymethylaminocarbonyl)-3,7-bis(dimethylamino)phenothiazine that anticipates or renders obvious the subject matter of the rejected claims.

Without wishing to acquiesce to the correctness of this rejection, the Applicants can establish that the claimed subject matter was reduced to practice by the inventors prior to October 26, 1999, the date at which Smith's patent was granted and became art under 35 U.S.C. §102(a) and §103(a).

As set forth in 37 C.F.R. §1.131:

(a) When any claim of an application or a patent under reexamination is rejected, the inventor of the subject matter of the rejected claim, the owner of the patent under reexamination, or the party qualified under §§1.42, 1.43, or 1.47, ***may submit an appropriate oath or declaration to establish invention of the subject matter of the rejected claim prior to the effective date of the reference*** or activity on which the rejection is based. . . .

(b) ***The showing of facts shall be such, in character and weight, as to establish reduction to practice prior to the effective date of the reference***, or conception of the invention prior to the effective date of the reference coupled with due diligence from

prior to said date to a subsequent reduction to practice or to the filing of the application. .

(emphasis added)

As such, a 35 U.S.C. §102(a) or 35 U.S.C. §103(a) rejection may be withdrawn if the Applicants can establish, by means of a declaration and a showing of facts, that the claimed subject matter was reduced to practice prior to the publication date of the cited reference.

In order to establish that the claimed invention was reduced to practice prior to the October 26, 1999 publication date of Smith, the Applicants submit herewith the Declaration of Koon-wah Leong under 37 C.F.R. §1.131. This declaration provides a showing of facts that the inventors reduced to practice the claimed invention prior to the October 26, 1999 publication date of Smith in that the inventors had reduced to practice a stable composition containing a nylon matrix and 10-(carboxymethylaminocarbonyl)-3,7-bis(dimethylamino)phenothiazine.

Since the Applicants have provided a declaration and facts that show a reduction to practice prior to the October 26, 1999 publication date of Smith, these rejections of claims 1, 6-11 and 16-27 under 35 U.S.C. §102(a) or 35 U.S.C. §103(a) may be withdrawn.

**Rejection under 35 U.S.C. §112, second paragraph**

Claims 6-10 and 16-27 are rejected under 35 U.S.C. §112, second paragraph, as being indefinite for reciting the word “system”. In making this rejection, the Office states “In claim 6 “system” is not understood in context; does it refer to an apparatus or composition?” and “It is the examiner’s position that Applicants argument that those skilled in the art look to the patent specification rather than the claims to apprise themselves of its teachings borders on the frivolous. The principle is well established that the claims must be understandable and stand on their own”. The Applicants respectfully traverse this rejection.

The MPEP at § 2173.05(a) provides very clear guidance for terminologies that may be used in a claim:

*While a term used in the claims may be given a special meaning in the description of the invention, generally no term may be given a meaning repugnant to the usual meaning of the term. In re Hill, 161 F.2d 367, 73 USPQ 482 (CCPA 1947). However, it has been stated that consistent with the well-established axiom in patent law that a patentee is free to be his or her own lexicographer, a patentee may not use terms in a manner contrary to or inconsistent with one or more of their ordinary meanings. (emphasis added).*

Further, the MPEP at § 2173.01 states that a “claim may not be rejected solely because of the type of language used to define the subject matter for which patent protection is sought”. (emphasis added).

As such, according to the law and the MPEP, the Office should focus on whether a term would be understood by a skilled person in view of the specification, not whether a term is understandable on its own. The Applicants previous arguments are therefore not frivolous, as asserted by the Examiner – they are consistent with what is taught in the MPEP and by the law.

In this regard, the section starting on page 6, line 4 of the specification provides a detailed explanation of what is meant by a “signal producing system”. The specification therefore explains what a signal producing system is, how it works, and which components may part of the system. The Applicants respectfully submit that this section, as well as the remainder of the specification, makes clear what is meant by “signal producing system” in the rejected claims. This is all that is required to meet the standards set forth in the MPEP and all that is required by the law.

Further, a search of the U.S.P.T.O. patent database reveals that the word “system” has been recited in 490,343 issued US patents (approximately 7.5% of all issued patents under the current numbering system). The word “system” appears to be a commonly found word in issued claims.

As such, the Applicants respectfully submit that there is no doubt that the meaning of the phrase “system” is clear.

In view of the foregoing, withdrawal of this objection is respectfully requested.

#### **New claims**

Claims 28-34 are new and correspond to claims 1-3, 11-13 and 34, as originally filed.

The Applicants have established, by means of a Declaration under 37 C.F.R. §1.131, that the claimed invention was reduced to practice prior to October 26, 1999, the publication date of Smith (U.S. Patent No. 5,972,294).

Smith is the only art cited against original claims 1-3, 11-13 and 34. Since Smith has been disqualified as a prior art reference by a Declaration, the Applicants respectfully submit that new claims 28-34, corresponding to original claims 1-3, 11-13 and 34, are also patentable over Smith.

Accordingly, allowance of claims 28-34 is respectfully requested.

**CONCLUSION**

In view of the above remarks, this application is considered to be in good and proper form for allowance and the Examiner is respectfully requested to pass this application to issue. If the Examiner finds that a Telephone Conference would expedite prosecution of this application, he is invited to contact the undersigned (650) 327-3400.

In the event that the transmittal letter is separated from this document and the Patent Office determines that extensions or other relief is required and/or fees are due applicants, the Applicant petitions for any required relief, including extensions of time, and authorize the Commissioner to charge our Deposit Account No. 50-0815, Order Number LIFE008, for any fees due in connection with the filing of this document. The Patent Office is not authorized to charge issue fees to our Deposit Account.

Respectfully submitted,  
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